Paper No. 16

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte PETER J. POHNDORF

Appeal No. 2000-0323
Application No. 08/608,920

ON BRIEF

Before McCANDLISH, Senior Administrative Patent Judge, ABRAMS and NASE, Administrative Patent Judges.

NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1 to 6 and 8 to 20, which are all of the claims pending in this application.

We AFFIRM-IN-PART.

BACKGROUND

The appellant's invention relates generally to an introducer system for a lead or catheter employing a dilator and introducer sheath assembly for dilating a body vessel in preparation of introducing the lead or catheter through the lumen of the introducer sheath that provides for the injection of radiopaque contrast media to observe the cause of an impediment to advancement of the assembly into the vessel lumen (specification, p. 1). A copy of the claims under appeal is set forth in the appendix to the appellant's brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Lee	5,312,355	May 17, 1994
Ruggio	5,476,450	Dec. 19, 1995

(filed Jan. 5, 1994)

Claims 15 to 20 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the appellant, at the time the application was filed, had possession of the claimed invention.

Claims 1 to 6, 8 to 11 and 14 to 20 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Ruggio.

Claims 12 and 13 stand rejected under 35 U.S.C. § 103 as being unpatentable over Ruggio in view of Lee.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellant regarding the above-noted rejections, we make reference to the final rejection (Paper No. 11, mailed January 23, 1998) and the answer (Paper No. 15, mailed December 7, 1998) for the examiner's complete reasoning in support of the rejections, and to the brief (Paper No. 14, filed July 23, 1998) for the appellant's arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellant's specification and claims, to the applied prior art references, and to the respective positions articulated by the appellant and the examiner. As a consequence of our review, we make the determinations which follow.

The written description rejection

We sustain the rejection of claims 15 to 20 under 35 U.S.C. § 112, first paragraph.

The test for determining compliance with the written description requirement is whether the disclosure of the application as originally filed reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter, rather than the presence or absence of literal support in the specification for the claim language. See Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991) and In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983).

Claim 15 recites an introducer system for dilating a body vessel comprising, inter alia, a dilator having a first stiffness and an elongated introducer sheath having a second stiffness wherein the second stiffness is less than the first stiffness.

The examiner determined (final rejection, p. 3) that the recitation in independent claim 15 that the second stiffness is less than the first stiffness (i.e., the stiffness of the elongated introducer sheath is less than the stiffness of the dilator) lacked written description support in the original application. We agree.

We have reviewed the originally filed disclosure and find no express disclosure for the above-noted limitation of claim 15. In addition to an express disclosure, the written description requirement can be satisfied by showing that the disclosed subject matter, when given its "necessary and only reasonable construction," inherently (i.e., necessarily) satisfies the limitation in question. See Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1423, 5 USPQ2d 1194, 1198

(Fed. Cir. 1987), cert. denied, 486 U.S. 1008 (1988). While there is an inherent disclosure as to the basic geometry of the elongated introducer sheath and the dilator as shown in Figures 15-17, it is our view that such inherent geometry is insufficient to necessarily suggest that the stiffness of the elongated introducer sheath is less than the stiffness of the dilator as set forth in the above-noted limitation from claim 15. In that regard, we note that a disclosure that merely renders the later-claimed invention obvious is not sufficient to meet the written description requirement; the disclosure must describe the claimed invention with all its limitations. See Tronzo v. Biomet Inc., 156 F.3d 1154, 1158-60, 47 USPQ2d 1829, 1832-34 (Fed. Cir. 1998); Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1571-72, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); Vas-Cath Inc., 935 F.2d at 1563-64, 19 USPQ2d at 1117; In re Winkhaus, 527 F.2d 637, 640, 188 USPQ 129, 131 (CCPA 1975); In re DiLeone, 436 F.2d 1404, 1405, 168 USPQ 592, 593 (CCPA 1971); In re Wohnsiedler, 315 F.2d 934, 937, 137 USPQ 336, 339 (CCPA 1963).

For the reasons set forth above, we find the appellant's argument (brief, p. 4) unpersuasive that the original application and in particular Figures 15 and 17 would reasonably convey to one skilled in the art the above-noted limitation from claim 15. In addition, we note that since Figures 15 and 17 are not drawn to scale, the original disclosure does not support the appellant's characterization of the introducer sheath as being "relatively thin walled" and the characterization of the dilator as being "relatively thick." In our view, it is not possible to determine the relative wall thickness of the introducer sheath and dilator.

For the reasons set forth above, the decision of the examiner to reject claims 15 to 20 under 35 U.S.C. § 112, first paragraph, is affirmed.

The anticipation rejection

We will not sustain the rejection of claims 1 to 6, 8 to 11 and 14 to 20 under 35 U.S.C. § 102(e).

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or

inherently described, in a single prior art reference. Verdegaal Bros. Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir.), cert. denied, 484 U.S. 827 (1987). The inquiry as to whether a reference anticipates a claim must focus on what subject matter is encompassed by the claim and what subject matter is described by the reference. As set forth by the court in Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 772, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984), it is only necessary for the claims to "'read on' something disclosed in the reference, i.e., all limitations of the claim are found in the reference, or 'fully met' by it."

Ruggio discloses an apparatus and technique for aspirating substances partially or completely occluding blood vessels or chambers of the heart. The aspirator assembly comprises a catheter assembly and a suction member for aspirating substances through the catheter. The catheter assembly comprises a catheter which travels over a guidewire. Exemplary suction members used for aspirating include a

syringe or a vacuum reservoir. The method of treating the intravascular site comprises the steps of advancing a catheter assembly through a patient's vasculature until a distal end of the catheter assembly reaches an area close to the site, and aspirating occluding substances in the vicinity of the site through the distal end of the catheter assembly. The method may also include the additional steps of introducing medication through the catheter, and pulverizing the occlusion or any of its residue, prior to aspirating the occluding substances.

Ruggio teaches (column 7, line 20, to column 8, line 31)

> [i]n treating pulmonary embolism, access to the main pulmonary arteries 88, 90 is generally made through the right or left femoral vein 80, 82 located in either the right or the left thigh 92, 94, as shown in FIG. 3. A Cook needle (not shown) is first used to puncture the vein 80 or 82. The Cook needle is commercially available from Cook Incorporated in Bloomington, Ind. In one embodiment, a conventional J-tipped guidewire (not shown) is then inserted into the needle into the artery or vein. The needle is then removed.
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> Next, a conventional sheath assembly (not shown) comprising a dilator and a sheath, is advanced over the J-tipped guidewire and inserted into the vein 80 or 82. As is known, such conventional sheath assemblies are generally equipped with a side arm for flushing. Once the sheath assembly is in place, the J-tipped guidewire and

the dilator are removed and the sheath assembly is flushed with saline solution through the side arm of the sheath assembly. An appropriate catheter assembly 12, for example, a catheter 22 with a J-tipped guidewire 24 (see FIG. 1) or a straight tip guidewire (not shown), is then advanced through the sheath to the intravascular site or heart chamber under examination. The tip of the guidewire 24 is always advanced ahead of the elongated tube portion 26 of the catheter 22, to minimize any risk of damage to the walls of the blood vessel. In one embodiment, the catheter 22 may be advanced through the sheath to the intravascular site or heart chamber without the use of a guidewire 24. An exemplary catheter for such use is a conventional multipurpose catheter or a balloon-tipped catheter.

As depicted in FIGS. 1 and 3, to reach the main pulmonary arteries 88, 90, the catheter assembly 12 is first advanced up the femoral vein 80 or 82, with the connector 28 of the catheter assembly 12 remaining outside the vein 80 or 82. The catheter assembly 12 is then connected to the manifold 14 and the catheter assembly 12 is flushed vigorously. To flush the catheter assembly 12, the control valve 42, 44 or 46 regulating the flow of saline solution is opened. The required amount of saline is drawn into the syringe 18. Next, the valve 42, 44 or 46 is closed and the saline may then be injected into the vessel or chamber under treatment. Medication may also may administered in the same manner.

Under pressure monitoring and/or fluoroscopic guidance, the catheter assembly 12 is advanced through the right or left common iliac 96 or 98 and the inferior vena cava 100, into the right atrium 102. The catheter assembly 12 is then advanced through the tricuspid valve (not shown) into the right ventricle 104, up the pulmonary trunk 106, and henceforth into the right or left main pulmonary artery 88 or 90. Once the catheter assembly 12 reaches the pulmonary trunk 106, or the cardiac chambers 102, 104, a radiopaque contrast agent may be injected through the connector 28 of the catheter

> 22, to facilitate fluoroscopic guidance of the catheter assembly 12 into the pulmonary artery 88 or 90. Typical contrast agents used include ionic contrast agents such as Renograffin or MD 76, or nonionic contrast agents such as Optiray or Hexabrix. Renograffin is commercially available through Bristol-Myers Squibb Diagnostics in Princeton, N.J. MD 76, Optiray and Hexabrix are all commercially available from Mallinckrodt Incorporated in St. Louis, Mo.
>
> Selective injection of the radiographic contrast agent into the cardiac chambers 102, 104, pulmonary trunk 106 or pulmonary vessels 88, 90, 108, 110 facilitates contrast radiographic inspection of the vessel, which in turn permits the placement of the catheter assembly 12 into the intravascular site of interest. A contrast agent is also injected into the site under examination during recording of radiographic images. Each vessel is usually viewed in several projections, to permit assessment of severity of stenosis or occlusive emboli and to minimize overlap of adjacent vessels. Injecting the contrast agent into the pulmonary system also facilitates the location of occlusions such as clots in the pulmonary vessels 108, 110.
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> Under fluoroscopic guidance, the catheter assembly 12 is advanced to the occluded pulmonary artery. Next, the guidewire 24 may be withdrawn from the catheter assembly 12 and treatment of the intravascular site in accordance with the present invention begins. The guidewire 24 may, however, be left in place during treatment.

Ruggio further teaches that the catheter assembly 12 is conventional, and comprises a catheter 22 which travels over a steerable guidewire 24, as is known in the art. The catheter

22 comprises an elongated, flexible tube 26 attached to a connector 28 (see Figures 1, 4 and 5). As shown in Figure 4, the elongated flexible tube portion 26 of catheter 22 is positioned close to an occlusion 120 in the pulmonary vessel 122 once the position of the occlusion 120 is determined. A thrombolytic agent is then administered to the occlusion 120, as depicted by arrows
124 through the tube 26 of catheter 22 via one of the T-connectors 36, 38 or 40 of the manifold 14 (see Figure 1). If the thrombolytic agent acts sufficiently to break the occlusion 120 into small enough pieces, the residue 126 of the occlusion 120 is aspirated immediately by means of a syringe 18 or a vacuum reservoir, as depicted by the arrows 140 shown in Figure 5. Aspiration of the residue 126 is accomplished by first placing the tip of the elongated tube 26 of catheter 22 close to the residue 126 of the occlusion 120 under fluoroscopic guidance. Next, the plunger 52 of the syringe 18 is drawn backwards (see Figure 1), which creates a pressure difference to draw the residue 126 of the occlusion 120 into the syringe 18. When the occlusion 120 or its residue 126 has been removed, the tube 26 of catheter 22 may be advanced under

fluoroscopic guidance to vessels downstream, so that occlusions 121 further downstream may be similarly removed. If the thrombolytic agent does not break the occlusion 120 into sufficiently small pieces for immediate aspiration through the catheter 22, the guidewire 24 in the catheter assembly 12 is used to manually pulverize the occlusion 120 or its residual pieces 126 into particles small enough to be aspirated, as shown in Figures 4 and 5. The catheter assembly 12 may first be disconnected from the manifold 14 prior to performing this procedure. If the guidewire 24 has been removed during an earlier part of the procedure, it may be reintroduced into the catheter 22 so that pulverization of the occlusion 120 may be performed. When the residue 126 has been pulverized into particles small enough to pass through the catheter 22, the plunger 52 of the syringe 18 is drawn backwards, drawing the residue 126 of the occlusion 120 into the syringe 18. When contrast radiographic inspection indicates that there is no evidence of any remaining residual occlusions 126, the catheter 22 is removed.

Ruggio further discloses with reference to Figure 6, an improved aspirator assembly 210 comprises a catheter assembly 212 connected to a y-connector 214 at the distal end 216 of the y-connector 214, a connector assembly 218 connected to the proximal end 220 of the y-connector 214 and an evacuation module 222 which is connected to the proximal end 224 of the connector assembly 218. The aspirator assembly 210 further comprises an infusion assembly 226 which is connected to a side arm 228 of the y-connector 214. The catheter assembly 212 comprises a catheter 236 which travels over a steerable guidewire 238. The catheter 236 comprises an elongated, flexible tube 240 attached to a connector 242. Preferably, and as illustrated in Figure 8a, the elongated tube 240 defines a first lumen 244 (for the guidewire 238) and a second lumen 246 (for aspiration of occlusions and for introducing various fluids such as saline, which is used for flushing the catheter 22; a radiopaque contrast agent, which is used to determine the patency of the vessel or chamber under fluoroscopic examination, or for providing fluoroscopic guidance of the catheterization process; or any medication required), which are separated by a partition 248. In this

embodiment, the first lumen 244 has a smaller cross-sectional area than the
second lumen 246. In addition, Ruggio teaches (column 11, lines 34-37) that "the tip of the catheter 236 may be configured in a variety of shapes, depending on the intended application. The catheter 236 may have a straight tip, an angled tip or a pig-tail tip, as is known in the art."

Claims 1 to 6, 8 to 11 and 15 to 20 recite an introducer system comprising, inter alia, a dilator and an elongated introducer sheath. Claims 1 to 6 and 15 to 20 also recite means integrally formed with the dilator for introducing contrast media adjacent the distal end of the dilator. Claims 8 to 11 also recite a contrast injection lumen formed in the dilator body isolated from the guide wire lumen and terminating in an injection port in the distal end of the dilator. Claim 14 recites a method of introducing an introducer sheath into a body including the steps of providing an introducer sheath and providing a dilator having a guide

wire lumen and a contrast media injection lumen terminating in an injection port in the distal end of the dilator.

It is the position of the examiner (final rejection, pp. 4-5; answer, pp. 4-6) that the claimed "dilator" is readable on Ruggio's catheter (22, 236). It is the position of the appellant (brief, pp. 4-6) that the claimed "dilator" is not readable on Ruggio's catheter (22, 236). We agree with the appellant. In our view one of ordinary skill in the art would not regard Ruggio's catheter (22, 236) as being "a dilator." We reach this conclusion based on (1) Ruggio's own teaching (column 7, lines 29-40) that a conventional **dilator** and a sheath are advanced over a J-tipped guidewire inserted into a vein, thereafter the dilator is removed, and then an appropriate **catheter** is advanced through the sheath to the intravascular site or heart chamber under examination; and (2) the appellant's argument that "a dilator is not a catheter" since a dilator is rigid while a catheter is flexible. Thus, it is our determination that the claimed "dilator" is not readable on Ruggio's catheter (22, 236) since Ruggio's

catheter (22, 236) includes the elongated flexible tube (26, 240).

For the reasons set forth above, the claimed dilator is not readable on Ruggio's catheter. Accordingly, the decision of the examiner to reject claims 1 to 6, 8 to 11 and 14 to 20 under 35 U.S.C. § 102(e) is reversed.

The obviousness rejection

We have reviewed the reference to Lee applied in the 35 U.S.C. § 103 rejection of claims 12 and 13 but find nothing therein which makes up for the deficiency of Ruggio discussed above.[1] Accordingly, the decision of the examiner to reject claims 12 and 13 under 35 U.S.C. § 103 is reversed.

CONCLUSION

[1] Claims 12 and 13 recite an introducer system comprising, inter alia, a dilator, an elongated introducer sheath and means integrally formed with the dilator for introducing contrast media adjacent the distal end of the dilator.

To summarize, the decision of the examiner to reject claims 15 to 20 under 35 U.S.C. § 112, first paragraph, is affirmed; the decision of the examiner to reject claims 1 to 6, 8 to 11 and 14 to 20 under 35 U.S.C. § 102(e) is reversed; and the decision of the examiner to reject claims 12 and 13 under 35 U.S.C. § 103 is reversed.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

HARRISON E. McCANDLISH Senior Administrative Patent Judge	)
NEAL E. ABRAMS Administrative Patent Judge	) BOARD OF PATENT) APPEALS) AND) INTERFERENCES
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